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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/620,712	07/16/2003	Crystal Cunanan	ECV-5665	9590

30452 7590 09/25/2006

EDWARDS LIFESCIENCES CORPORATION  
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IRVINE, CA 92614

EXAMINER
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MCKANE, ELIZABETH L

ART UNIT	PAPER NUMBER
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1744

DATE MAILED: 09/25/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

10/620,712

Applicant(s)

CUNANAN ET AL.

Examiner

Leigh McKane

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☐ Responsive to communication(s) filed on \_\_\_\_.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-24 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-24 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 16 July 2003 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
  - ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
  - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- ☒ Notice of References Cited (PTO-892)
- ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- ☒ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date 012004.
- ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- ☐ Notice of Informal Patent Application
- ☐ Other: \_\_\_\_.

***Claim Rejections - 35 USC § 103***

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

4. Claims 1-3, 5, 6-22, and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carpentier et al. (WO 98/56432) in view of Nashef et al. (WO 84/01879).

With respect to claims 1-3, 5, 6, 8-20, 22, and 24, Carpentier et al. teaches a method of

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treating a bioprosthesis (heart valve) wherein the bioprosthesis is fixed with a glutaraldehyde solution, initially sterilized in an alcohol/formaldehyde solution, and terminally sterilized in a formaldehyde-containing liquid solution at a temperature of 34-38 °C. See Figure 1. The initial sterilization solution is disclosed to contain formaldehyde, ethanol, and Tween 80. See page 9, lines 9-17. Carpentier et al. does not disclose adding a surfactant to the fixing solution.

Nashef et al. discloses the use of a surfactant in combination with glutaraldehyde in a fixing solution for mitigating calcification in implantable biological tissues. See Abstract. Nashef et al. teaches that the surfactant, such as Tween 80, may be used in an amount of about 0.1 to about 10 % w/v. See page 6, line 36 to page 7, line 9; Example VI.

It would have been obvious to one of ordinary skill in the art at the time of the invention to add a surfactant, such as Tween 80, to the glutaraldehyde fixing solution of Carpentier et al., in order to mitigate calcification of the tissue, as disclosed by Nashef et al..

As to claim 7, since Carpentier et al. already teaches fixing the tissue in the absence of a surfactant or a denaturant, it would have been obvious to achieve the results of Nashef et al. by contacting the *fixed* tissue of Carpentier et al. with the surfactant/glutaraldehyde solution.

With respect to claim 21, it is deemed obvious to provide redundancies in the method of Carpentier et al., wherein the tissue is undergoes a preliminary step of pathogen reduction using the sterilizing solution of Carpentier et al., before the fixing step and the two final sterilization steps, as it has been held obvious to duplicate steps for a multiplied effect.

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5. Claims 4 and 23 are rejected under 35 U.S.C. 103(a) as being unpatentable over Carpentier et al. and Nashef et al. as applied to claims 1 and 23 above, and further in view of Cunanan et al. (WO 02/43778).

Carpentier et al. with Nashef et al. does not recognize the reduction of phospholipids content in the biological material. However, Cunanan et al. evidences that it was known in the art at the time of the invention that treatment of a biological tissue with a solution containing ethanol, Tween 80, and glutaraldehyde is effective in removing phospholipids. See page 14, lines 3-9; page 16, lines 15-30. Thus, treatment of a biological tissue using the method of Carpentier et al. with Nashef et al. will intrinsically achieve reduction of phospholipids content therein.

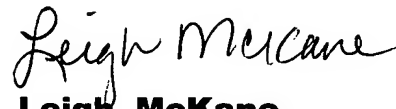
#### ***Conclusion***

6. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Leigh McKane whose telephone number is 571-272-1275. The examiner can normally be reached on Monday-Friday (5:30 am-2:00 pm).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gladys Corcoran can be reached on 571-272-1214. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.



**Leigh McKane**  
**Primary Examiner**  
**Art Unit 1744**

elm  
19 September 2006